REMARKS

Claims 18-20, 23, 24, 27, 30, 31, 33, 34, 37, and 41-50 are currently pending in this application. Claims 20, 27 and 37 have been amended to recite "consisting of" rather than "comprising" in the preamble in response to the Examiner's statements on page 4 of the Office Action. No new matter has been introduced. Reconsideration of the pending claims in view of the arguments/comments below is respectfully requested.

Rejections under 35 U.S.C. § 103

In the Outstanding Office Action and the Office Action of February 27, 2006, Claims 18-20, 23, 24, 27, 30, 31, 33, 34, 37, and 41-50 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Paul, et al. (hereinafter "Paul") and Van Loo, et al. (hereinafter "Van Loo") for the reasons set forth on pages 3-4 of the Office Action.

Applicants respectfully traverse the rejection.

When applying 35 U.S.C. § 103, the Examiner is required to adhere to the following tenets of patent law: (1) The claimed invention must be considered as a whole; (2) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (3) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (4) Reasonable expectation of success is the standard with which obviousness is determined. *Hodosh v. Block Drug Co., Inc.,* 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

Furthermore, to establish a prima facie case of obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d

981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

Independent Claim 20, as amended, is directed to a method for the treatment of infections in humans or vertebrates consisting of: administering to humans or vertebrates having an infection caused by an invasion of the blood stream or lymph by a pathogen selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida* and *Salmonella*, a composition consisting essentially of an effective amount of inulin and/or oligofructose to treat said infection; and one or more pharmaceutically acceptable excipients, wherein the composition is administered orally or through tube feeding.

Independent Claim 27, as amended, is directed to a method for the treatment of an infection occupying the lymph or blood in humans or vertebrates consisting of: administering to humans or vertebrates having an infection caused by a pathogen selected from the group consisting of *Clostridia, Bacteroides, Listeria, Candida, Listeria* and *Salmonella* in the lymph or blood, a composition consisting essentially of an effective amount of inulin and/or oligofructose to treat said infection; and one or more pharmaceutically acceptable excipients, wherein the composition is administered orally or through tube feeding.

Independent Claim 37, as amended, is directed to a method for the treatment of infections in humans or vertebrates, consisting of administering to humans of vertebrates having an infection caused by an invasion of the blood stream or lymph by a pathogen selected from the group consisting of Clostridia, Bacteroides, Listeria, Candida and Salmonella, a functional food composition consisting essentially of an effective amount of

7

~WASH1:4752576.v1

inulin and/or oligofructose to treat said infection; wherein the food composition is administered orally or through tube feeding.

In contrast, as admitted by the Examiner, <u>Paul</u> generally describes a composition that lowers the intestinal pH and inhibits the overgrowth of gastrointestinal pathogens.

<u>Paul</u> does not mention anything about the use of inulin and/or oligofructose treating established infections in humans and vertebrates caused by an invasion of the blood stream or lymph by a pathogen selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida* and *Salmonella*. Accordingly, applicants respectfully submit that <u>Paul</u> does not render Claims 20, 27 and 37 obvious because <u>Paul</u> fails to teach or suggest every limitation of the claimed invention.

Van Loo does not cure the deficiency of Paul. Van Loo generally describes a method for treating colon cancer with a composition comprising dietary fiber. Van Loo, however, is absolutely silent with respect to the possible use of inulin and/or oligofructose for the treatment of established infections in humans and vertebrates caused by an invasion by pathogenic bacteria of the lymph or the blood stream. Therefore, Van Loo fails to teach or suggest treating "an infection caused by an invasion of the blood stream by Listeria or Salmonella."

Applicants respectfully submit that <u>Paul</u>, et al. and <u>Van Loo</u>, et al., taken alone or in combination, are absolutely silent regarding using inulin and/or oligofructose for treating established infections in humans and vertebrates caused by an invasion of a pathogenic bacteria of the lymph or the blood stream. Neither <u>Paul</u> nor <u>Van Loo</u> provides any incentive to the skilled person to consider oral administration or administration via tube feeding of inulin/oligofructose to treat said infections in humans and vertebrates

8

~WASH1:4752576 v1

Moreover, neither Paul nor Van Loo provides a reasonable expectation of success in using inulin and/or oligofructose for the treatment of established infections in humans and vertebrates caused by an invasion of the lymph or the blood stream by Listeria or Salmonella. As discussed above, Paul describes inhibition of harmful bacteria in the gastrointestinal tract and Van Loo describes inhibition of cancer growth in the colon. Neither Paul nor Van Loo discloses or suggests using inulin and/or oligofructose for treating established infections in humans and vertebrates caused by an invasion of a pathogenic bacteria of the lymph or the blood stream. One skilled in the art would not be able to produce the invention of Claims 20, 27 and 37 based on Paul and Van Loo without undue experimentation. Consequently, the unexpectedly superior effect of the claimed inventions render them not obvious to one skilled in the art to derive the present invention from the prior art of record.

Accordingly, <u>Paul</u> and <u>Van Loo</u>, individually or in combination, do not render independent Claims 20, 27 and 37 obvious.

Applicants further submit that Claims 18-19, 23, 24, 30, 31, 33, 34, and 41-50 are patentable because they depend from Claims 20, 27 or 37 and define additional patentable subject matter.

Therefore, the references of <u>Paul</u> and <u>Van Loo</u> do not support a *prima facie* case of obviousness. The grounds for this rejection have been obviated and withdrawal of the 35 U.S.C. § 103 rejection is respectfully requested.

CONCLUSION

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to contact Ping Wang, M.D. (Reg. No. 48,328) at the telephone number listed below.

Respectfully submitted,

DLA PIPER RUDNICK GRAY CARY US LLP

James M. Heintz

Registration No. 41,828

Ping Wang

Registration No. 48,328

1200 Nineteenth Street, N.W. Washington, D.C. 20036-2412 Telephone No. (202) 861-3900 Facsimile No. (202) 223-2085

10